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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,596	09/29/2003	Coni Rosati	99866/14	2412

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,596	ROSATI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-48* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29 and 31-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/06; 2/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Applicant's election of claims directed to method of using bioactive material (Group II) in the reply filed on 02/07/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 30 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 27-48 are pending in this action. Claim 30 has been withdrawn (non-elected species). New claims 27-48 have been added. Claims 1-26 have been cancelled. Claims 27-29 and 31-48 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claim 44 is objected to because of the following informalities:

Claim 44 is a duplicate of claim 40. Appropriate correction is required.

* * * * *

Double Patenting

Claims 27-29 and 31-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-45 of copending Application No. 10/696,878 ('878 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and the copending '878 application.

More specifically, both the instant composition and the '878 application claim a method for abrading human or animal tissue that comprises contacting the tissue with an abrasive material or bioglass material. Additionally, both the instant application and the '878 application claim the same abrasive (or bioglass) materials such as silicon dioxide (SiO_2), sodium oxide (Na_2O) and calcium oxide (CaO) (see instant claim 32 & claims 26-27 of '878).

It is noted that different and varying amounts of the abrasive materials (*i.e.*,(SiO_2) are claimed in each application. However, generally differences in concentration will not support

the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, the determination of suitable or effective amounts can be carried out through manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the level of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Claims 27-29 and 31-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 7,141,520 ('520 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and the '520 Patent.

More specifically, '520 Patent teaches a similar glass composition comprising the same materials, such as silicon dioxide (SiO_2), sodium oxide (Na_2O), calcium oxide (CaO) and phosphorous oxide (P_2O_5), which is also employed in the instant method of abrading tissue (method of using) (see instant claim 32 & claims 1-2 of '520). The composition claimed in the '520 Patent is provided for in the method of abrading tissue claimed in the instant application.

It is noted that different and varying amounts of the materials (*i.e.*, (SiO_2) are claimed in the instant application and '520 Patent. However, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, the determination of suitable or effective amounts can be carried out through manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the level of one of ordinary skill in the art.

This is a double-patenting rejection.

* * * * *

Claims 27-29 and 31-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,192,602 ('602 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and the '602 Patent.

More specifically, '602 Patent teaches a similar glass composition comprising the same materials, such as silicon dioxide (SiO_2), sodium oxide (Na_2O), calcium oxide (CaO) and phosphorous oxide (P_2O_5), which is also employed in the instant method of abrading tissue

(method of using) (see instant claim 32 & claim 1 of '602). The composition claimed in the '602 Patent is provided for in the method of abrading tissue claimed in the instant application.

It is noted that different and varying amounts of the materials (*i.e.*, (SiO_2) are claimed in the instant application and '602 Patent. However, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, the determination of suitable or effective amounts can be carried out through manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the level of one of ordinary skill in the art.

This is a double-patenting rejection.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-29 and 31-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaTorre *et al.* (U.S. Pat. No. 6,517,863) in view of Greenspan *et al.* (U.S. Pat. No. 6,756,060).

The instant invention is drawn to a method for abrading human or animal tissue comprising contacting the tissue with a bioactive material.

LaTorre *et al.* ('863) teach compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties, alone or in combination with therapeutic agents, hydrophilic polymers and other additional agents (see Abstract).

LaTorre *et al.* disclose that the bioactive glass compositions can include additional components, such as antibiotics, antivirals, antifungals, biotin, collagen, amino acids, proteins, vitamins, penetration enhancers, permeation/binding agents, dyes, fragrances and other cosmetically useful additives (col. 2, lines 62-66); (col. 5, lines 26-30). Bioactive glass also has anti-microbial properties (col. 2, line 67). These teachings read on Applicant's limitations of claims 40-43, for providing antimicrobial effect, anti-inflammatory effect, etc. For instance,

collagen, taught by LaTorre *et al.* would be effective for the promotion of wound healing (claim 43).

The glass preferably includes silicon dioxide (SiO_2) (between 40 and 86%); sodium oxide (Na_2O) (between about 0 and 35%); calcium oxide (CaO) (between about 4 and 46%) and phosphorous oxide (P_2O_5) (between about 1 and 15%) (col. 3, line 60 – col. 4, line 4). These teachings read on Applicant's claims 31-34.

The most preferred glass is Bioglass® (a trademark of University of Fla.), which has a composition including about 45% by weight silicon dioxide, about 24.5% by weight sodium oxide, about 6% by weight phosphorous oxide and about 24.5% by weight calcium oxide (col. 4, lines 11-19).

Particulate non-interlinked bioactive glass is preferred in the invention, whereby the glass is in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers (col. 4, lines 20-32).

According to LaTorre *et al.*, the bioactive glass composition can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles (col. 4, lines 33-45). The bioactive glass has a particle size of less than about 5 microns and can be in the form of a suspension, lotion, cream (water-in-oil emulsion), gel or extract (col. 4, lines 27-32; 51-67).

The Examples at columns 6-7 demonstrate various bioactive glass formulations for application to a nail surface. For instance, Example 1 at column 6, line 45 demonstrates a bioactive glass preparation whereby 0.2 grams of Bioglass® with a particle size of less than 20 microns was mixed with an equal volume of water to form a paste. The paste was applied to the

nails of one hand and allowed to dry. This procedure was repeated and after two applications of the Bioglass® powder, there was a discernable difference in the strength and hardness of the nails treated with the Bioglass® powder, compared to the untreated control.

LaTorre *et al.* do not teach that the bioactive material comprises mineral salts or oxides selected from copper, zinc, silver and magnesium.

Greenspan *et al.* ('060) teach bioactive glass-containing compositions comprising non-interlinked particles of bioactive glass wherein the compositions include antimicrobial salts, such as $AgNO_3$, CuO and ZnO, or other antimicrobial salts of the silver, copper and zinc ions (see reference column 4, lines 46-49) and Abstract. The salts offer antimicrobial and antibacterial effects to the bioglass compositions. Oxides disclosed include magnesium oxide (MgO) (col. 4, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate additive salts and/or oxides such as magnesium, silver, copper and/or zinc, as taught by Greenspan *et al.* within the bioglass compositions and methods taught by LaTorre et al. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Greenspan *et al.* teach bioactive glass-containing compositions that include antimicrobial salts of silver, copper and zinc ions and magnesium oxide, whereby the salts provide antimicrobial and antibacterial effects to the bioglass-containing compositions. The expected result would be an improved bioglass formulation that exhibits antimicrobial characteristics for enhanced healing promotion.

* * * * *

Claims 27-29 and 31-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaTorre *et al.* (U.S. Pat. No. 6,517,863) in view of Shimono *et al.* (U.S. Pat. No. 5,766,611).

The instant invention is drawn to a method for abrading human or animal tissue comprising contacting the tissue with a bioactive material.

LaTorre *et al.* ('863) teach compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties, alone or in combination with therapeutic agents, hydrophilic polymers and other additional agents (see Abstract).

LaTorre *et al.* disclose that the bioactive glass compositions can include additional components, such as antibiotics, antivirals, antifungals, biotin, collagen, amino acids, proteins, vitamins, penetration enhancers, permeation/binding agents, dyes, fragrances and other cosmetically useful additives (col. 2, lines 62-66); (col. 5, lines 26-30). Bioactive glass also has anti-microbial properties (col. 2, line 67). These teachings read on Applicant's limitations of claims 40-43, for providing antimicrobial effect, anti-inflammatory effect, etc. For instance, collagen, taught by LaTorre *et al.* would be effective for the promotion of wound healing (claim 43).

The glass preferably includes silicon dioxide (SiO_2) (between 40 and 86%); sodium oxide (Na_2O) (between about 0 and 35%); calcium oxide (CaO) (between about 4 and 46%) and

phosphorous oxide (P_2O_5) (between about 1 and 15%) (col. 3, line 60 – col. 4, line 4). These teachings read on Applicant's claims 31-34.

The most preferred glass is Bioglass® (a trademark of University of Fla.), which has a composition including about 45% by weight silicon dioxide, about 24.5% by weight sodium oxide, about 6% by weight phosphorous oxide and about 24.5% by weight calcium oxide (col. 4, lines 11-19).

Particulate non-interlinked bioactive glass is preferred in the invention, whereby the glass is in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers (col. 4, lines 20-32).

According to LaTorre *et al.*, the bioactive glass composition can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles (col. 4, lines 33-45). The bioactive glass has a particle size of less than about 5 microns and can be in the form of a suspension, lotion, cream (water-in-oil emulsion), gel or extract (col. 4, lines 27-32; 51-67).

The Examples at columns 6-7 demonstrate various bioactive glass formulations for application to a nail surface. For instance, Example 1 at column 6, line 45 demonstrates a bioactive glass preparation whereby 0.2 grams of Bioglass® with a particle size of less than 20 microns was mixed with an equal volume of water to form a paste. The paste was applied to the nails of one hand and allowed to dry. This procedure was repeated and after two applications of the Bioglass® powder, there was a discernable difference in the strength and hardness of the nails treated with the Bioglass® powder, compared to the untreated control.

LaTorre *et al.* do not teach that the bioactive material comprises mineral salts or oxides selected from copper, zinc, silver and magnesium.

Shimono *et al.* ('611) teach cosmetic compositions containing soluble glass particles. The cosmetic compositions contain soluble glass containing antibacterial metal ions that are selected from silver (Ag^{+}), copper ((Cu ($^{+/2+}$)) and zinc (Zn^{2+}). The cosmetic products exhibit excellent antibacterial property due to metal ions discharged from the soluble glass particles (see reference column 1, lines 14-17); (col. 2, lines 26-47). Metal oxides such as magnesium oxide (MgO) is also disclosed and functions as a network-strengthening component (col. 4, lines 36-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate additive salts and/or oxides such as magnesium, silver, copper and/or zinc, as taught by Shimono *et al.* within the bioglass compositions and methods taught by LaTorre et al. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Shimono *et al.* teach cosmetic products comprising soluble glass and metal ions such as silver, copper and zinc and magnesium oxide as a strengthening component, whereby the salts provide for excellent antibacterial effects to the cosmetic products. The expected result would be an enhanced formulation that beneficially combats bacterial activity.

* * * * *

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaTorre *et al.* (U.S. Pat. No. 6,517,863) in view of Burres (U.S. Pat. No. 6,471,712).

The instant invention is also drawn to a method for operating dermabrasion equipment comprising using the equipment to apply an abrasive material comprising a bioactive material to a human or animal tissue, whereby the dermabrasion equipment clogs substantially less than with abrasive materials not containing a bioactive material.

The teachings of LaTorre *et al.* are discussed above. LaTorre *et al.* do not teach a method of using a dermabrasion device to apply an abrasive material.

Burres ('712) teach methods and apparatus for performing dermabrasion procedures, such as abrading, cleaning, massaging, buffing and treating the skin, fingernails, toenails or other body surfaces using a dermabrasion device (see column 1, lines 13-15 and Abstract). The dermabrasion device may comprise abrasive materials such as diamond fragments (col. 2, lines 29-53). The device is equipped to minimize the likelihood of over abrading or injuring the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the methods of operating dermabrasion devices as taught by Burres within the bioglass compositions and methods taught by LaTorre et al. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Burres teaches methods and apparatus for abrading tissue through dermabrasion devices, which utilize abrasive materials (i.e., diamond fragments) and whereby the dermabrasion devices are simple to use and minimize over-abrading or injuring of the skin. The expected result would be an improved method of using dermabrasion devices to safely and effectively abrade tissues.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner
Art Unit 1615
April 25, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

hns